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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/802,315	03/08/2001	Archie Woodworth	1417 Y P 516	5264

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EXAMINER	
MCKANE, ELIZABETH L	
ART UNIT	**PAPER NUMBER**
1744	

DATE MAILED: 10/18/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/802,315	WOODWORTH ET AL.	
	Examiner	Art Unit	
	Leigh McKane	1744	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 July 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *76-78,80-94 and 105-108* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *76-78, 80-94, 105-108* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *08 March 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 105, 106, and 108 are rejected under 35 U.S.C. 102(b) as being anticipated by Erbe et al. (U.S. Patent No. 6,800,245).

Erbe et al. teaches a method for producing sterile prefilled syringe bodies wherein the method of Erbe et al. includes providing a syringe body (cartridge), transferring the body to a sterile environment (isolator) **70**, and sterilizing the cartridge with e-beam radiation in a step between providing the cartridges and transferring them to the sterile environment. Within the sterile environment, they are filled and sealed. See Figure 1; col.4, lines 34-37; col.6, lines 320; col.8, lines 17-20 and 30-32; col.12, lines 2-5, 19-27, 39-46.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. Claim 107 is rejected under 35 U.S.C. 103(a) as being unpatentable over Erbe et al..

Erbe et al. clearly teaches that the cartridges (syringes) are sterilized in a location other than the sterile isolator. Note that Erbe et al. discloses that only the steps of filling, assembling the piston, packaging the filled cartridges, and sealing the packages occur in the sterile isolator. See col.6, lines 14-18. Therefore, the cartridges *must* be transferred between the location where they are sterilized by e-beam radiation and the location where they are filled (isolator). It would have been obvious to one of ordinary skill in the art to accomplish this transfer in a sterile manner otherwise the sterile condition of the cartridges would have been compromised.

5. Claims 76-78, 80-87, 90, and 91 are rejected under 35 U.S.C. 103(a) as being unpatentable over Erbe et al (U.S. Patent No. 6,800,245) in view of Heffernan et al (U.S. Patent No. 5,620,425) and Nablo (U.S. Patent No. 3,780,308).

With respect to claims 76-78, 87, 90, and 91, Erbe et al teaches a method of sterilizing an injectable pharmaceutical wherein the cartridges (syringes), caps, and plunger pistons are sterilized using a dose of e-beam radiation, transferred into a sterile isolator (which is class 100 or greater), filled with a sterile fluid while within the sterile environment, and sealed within the sterile environment. See Figure 1; col.4, lines 34-37; col.6, lines 320; col.8, lines 17-20 and 30-32; col.12, lines 2-5, 19-27, 39-46. Erbe et al does not disclose forming the cartridges by injecting molding or arranging them on a transfer mechanism.

Heffernan et al teaches a method of making prefilled syringes wherein it is disclosed to first injection mold the syringes from polymeric materials (col.4, lines 41-53), followed by inspection (col.6, lines 3-11) and sterilization. It would have been obvious to form the syringes of Erbe et al using injection molding as this is a common and well-established means in the art

by which to construct medical syringes. Moreover, it would have been obvious to inspect the formed articles for size/shape conformity and cleanliness, given the ultimate use of the syringes in a sterile, medical environment.

Nablo discloses a method for the in-line production of sterile, filled containers wherein the containers are sterilized by e-beam radiation, filled, and sealed, all within a sterile environment. The containers are transported through the environment using a transfer mechanism (conveyor belt **8**). It would have been obvious to one of ordinary skill in the art to use a transfer mechanism in the method of Erbe et al, as such reduces human interaction and human error, as well as limits contamination from outside sources.

As to claims 82 and 86, although not expressed by Erbe et al, it would have been obvious to fill the syringes immediately after sterilization, in the manner of Nablo, in order to reduce the likelihood of contamination of the syringes prior to filling.

With respect to claim 83-85, Erbe et al teaches that it was known in the art to aseptically package and terminally sterilize various pharmaceuticals for injection. See col.3, lines 1-14. Therefore, it is deemed obvious to employ the general aseptic packaging techniques of Erbe et al for other sterile injectables, such as sterile water, and to maintain a suitable injection pH when doing so.

As to claims 80 and 81, Erbe et al does not disclose an irradiation dose for e-beam radiation of the syringes. Nablo teaches employing a radiation dose of 15 kGy for container sterilization. However, Nablo also employs high dose rates, such as 10^{14} rad/sec (10^{9} kGy/sec). See col.5, lines 16-19. It is deemed obvious to optimize and even increase the radiation dose

based upon the expected level of contamination, as such is easily obtained by routine experimentation.

6. Claims 88 and 89 are rejected under 35 U.S.C. 103(a) as being unpatentable over Erbe et al in view of Heffernan and Nablo, as applied to claim 87 above, and further in view of Porfano et al (U.S. Patent No. 6,164,044).

While the combination *supra* teaches forming a container from a polymeric material, inspecting it, sterilizing it, and then filling it, the combination of references fails to teach or suggest forming the container from a cyclic olefin copolymer. Porfano et al discloses that it was known in the art at the time of the invention to form containers intended for sterilizing and filling, of a cyclic olefin copolymer. See col.6, lines 44-47. As Porfano et al teaches that cyclic olefin copolymers do not require a clarifying agent, they would have been an economical choice for the containers of the combination.

7. Claims 92-94 are rejected under 35 U.S.C. 103(a) as being unpatentable over Erbe et al in view of Heffernan and Nablo, as applied to claim 75 above, and further in view of Liebert et al (U.S. Patent No. 5,207,983).

With respect to claim 92, Erbe et al does not disclose that the plunger has a plunger rod. However, Liebert et al evidences that this configuration is known in the art (col.6, lines 28-38) and absent unexpected results, it would have been obvious to use in the method of Erbe et al.

As to claim 93, Erbe et al discloses that it was known in the art to terminally sterilize some injectables. Furthermore, Liebert et al teaches terminal sterilization of a prefilled syringe. As terminal sterilization was known in the art at the time of the invention, when using the method of Erbe et al for the sterilization of other types of liquid injectibles, it is deemed obvious

to add the additional step of terminal sterilization in order to add a factor of safety to the sterilization method.

With respect to claim 94, Erbe et al teaches labeling the packaged assemblies. See col.6, lines 8-13; col.13, lines 11-14.

Response to Arguments

8. Applicant's arguments filed 27 July 2005 have been fully considered but they are not persuasive.

9. Applicant argues on page 6 of the Response that Erbe "has no disclosure whatsoever regarding the transfer of the cartridges into the sterile environment, let alone maintaining the syringe bodies in a sterile condition during transfer into the sterile environment." The Examiner respectfully disagrees with Applicant's assessment of the Erbe reference. Foremost, Erbe teaches the sterilization of the cartridges in a location separate from that where the cartridges are filled and packaged. As set forth in paragraph 4 *supra*, Erbe et al. discloses that only the steps of filling, assembling the piston, packaging the filled cartridges, and sealing the packages occur in the sterile isolator. See col.6, lines 14-18. Therefore, the cartridges *must* be transferred *from* the location where they are sterilized by e-beam radiation *to* the location where they are filled (isolator). It would have been obvious to one of ordinary skill in the art to accomplish this transfer in a sterile manner otherwise the sterile condition of the cartridges would have been compromised. Furthermore, it would have defied logic for the skilled practitioner to transfer the sterilized cartridges in a manner other than one which would have maintained their sterility as it would have destroyed the method of Erbe et al..

10. Applicant submits, with respect to Heffernan and Nablo, that neither teach or suggest transferring the sterilized syringes into a class 100 isolator. However, neither reference is required to teach this since the primary reference Erbe does. It is respectfully noted that Heffernan was relied upon for teaching the known use of injection molding for forming syringes and that Nablo was relied upon for an radiation dose for the sterilization of containers. Neither was relied upon for teaching the transferring of sterilized syringes into a class 100 isolator.

Conclusion

11. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leigh McKane whose telephone number is 571-272-1275. The examiner can normally be reached on Monday-Thursday (5:30 am-2:00 pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John Kim can be reached on 571-272-1142. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Leigh McKane
Leigh McKane
Primary Examiner
Art Unit 1744

elm
15 October 2005